

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**LISTING OF CLAIMS:**

1. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:
  - moving a reader head in a reflectance reader to a first position over the surface comprising the image;
  - measuring a first amount of light reflected from the surface comprising the image;
  - uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; and
  - uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, wherein the reader head comprises:
    - a reader head body;
    - a light emitting diode;
    - a first fiberoptic bundle optically coupled to the light emitting diode;
    - a photodetector;
    - a second fiberoptic bundle optically coupled to the photodetector;
    - an aperture in the reader head body; and
    - a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

2. (Cancelled)

3. (Previously Presented) The method of the claim 1, wherein the reflectance reader further comprises,

a control unit including a processor modified with a software subsystem, wherein the software subsystem is for analyzing data produced in the steps of determining the first, second and third amounts of light reflected from the surface.

4. (Previously Presented) The method of claim 1, further comprising performing an immunoassay on the test strip.

5. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; and

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, wherein the reflectance reader comprises:

the reader head comprising:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode, and adapted to transmit light from the light emitting diode;

a photodetector adapted for generating a reflection signal in response to reflected light;

a second fiberoptic bundle optically coupled to the photodetector, and adapted to transmit an amount of reflected light to the photodetector;

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

an aperture in the reader head body; and

a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle, the plurality of fiberoptic conductor ends being further arranged in a substantially co-planar relationship;

and a reader housing comprising:

a housing body; and

a cassette slot adapted to receive a test device.

6. (Previously Presented) The method of the claim 5, wherein the reflectance reader further comprises, a control unit including a processor modified with a software subsystem, wherein the software subsystem is for analyzing data produced from the steps of determining the first, second and third amounts of light reflected from the surface.

7. (Previously Presented) The method of claim 5, further comprising performing an immunoassay on the test strip.

8. (Previously Presented) The method of claim 1, further comprising determining a parameter correlated with the intensity or shape of the image, wherein the parameter is the amount of an analyte in a sample, which is a function of the first amount of light reflected, the second amount of light reflected, and the third amount of light reflected.

9. (Previously Presented) The method of claim 1, wherein the method further comprises determining an amount of an analyte in a sample by correlating a parameter with the amount of analyte in the sample.

10. (Cancelled)

11. (Previously Presented) The method of claim 1, wherein said first wavelength is selected to reflect equally from all regions of the test strip,

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

whereby said second amount of light is indicative of a test region of the test strip.

12. (Previously Presented) The method of claim 1, wherein said second wavelength reflects from a test region of the test strip, whereby said third amount of light is indicative of an amount of a label at the test region.

13. (Previously Presented) The method of claim 1, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.

14. (Previously Presented) The method of claim 5, further comprising determining an amount of an analyte in a sample, wherein the analyte is fetal fibronectin.

15. (Previously Presented) The method of claim 1, wherein the image comprises a stripe on the surface of the test strip.

16. (Previously Presented) The method of claim 1, further comprising: determining a parameter correlated with an intensity or shape of the image.

17. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface;

moving the reader head to a second position over the surface comprising the image;

measuring a fourth amount of light reflected from the second position on the surface comprising the image;

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

uniformly illuminating the second position on the surface with light of the first wavelength, and measuring a fifth amount of light reflected from the surface;

uniformly illuminating the second position on the surface with light of the second wavelength, and measuring a sixth amount of light reflected from the surface; and

determining a parameter correlated with an intensity or shape of the image.

18. (Currently Amended) A method for reading a surface of a test strip comprising an image, comprising:

(a) moving a reader head in a reflectance reader to a first position over the surface comprising the image;

(b) measuring a first amount of light reflected from the surface comprising the image;

(c) uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

(d) uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface;

(e) repeating each of ~~the measuring and illuminating steps~~ (b) through (d) at additional positions on the surface until the image on the surface of the test strip is scanned; and

(f) determining an intensity or shape of the image.

19. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

transmitting light of a first wavelength onto the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface; and

transmitting light of a second wavelength onto the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface.

20. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

with a reader head in a reflectance reader at a first position over the surface comprising the image, measuring a first amount of light reflected from the first position of the surface comprising the image;

transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface;

transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface;

moving the reader head to a second position over the surface comprising the image;

measuring a fourth amount of light reflected from the second position on the surface comprising the image;

transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and measuring a fifth amount of light reflected normally from the surface;

transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and measuring a sixth amount of light reflected normally from the surface; and

determining a parameter correlated with an intensity or shape of the image.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

21. (Currently Amended) A method for reading a surface of a test strip comprising an image, comprising:

(a) moving a reader head in a reflectance reader to a first position over the surface comprising the image;

(b) measuring a first amount of light reflected from the surface comprising the image;

(c) uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

(d) uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

(e) moving the reader head in a stepwise fashion to a plurality of positions over the test strip, wherein ~~three light measurements are made~~ steps (b) through (d) are repeated at each of the plurality of positions to determine an intensity or shape of the image.

22. (Previously Presented) The method of claim 1, wherein the step of measuring a first amount of light is carried out while no light is produced by a light source in the reader head.

23. (Previously Presented) The method of claim 1, wherein the first wavelength is blue.

24. (Previously Presented) The method of claim 1, wherein the second wavelength is amber.

25. (Previously Presented) The method of claim 1, wherein the measuring the first amount of light is used to determine an amount of background light.

26. (Previously Presented) The method of claim 1, wherein the measuring the second amount of light is used to determine levels of light reflections associated with the background of the bar code or the assay test strip.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

27. (Previously Presented) The method of claim 1, wherein the measuring the third amount of light is used to detect a symbology or the presence of an analyte on the test strip.

28. (Previously Presented) The method of claim 1, further comprising one or more steps selected from the group consisting of: (1) using the light measurements to correct for light leakage; (2) reducing the light measurements using a ratiometric formula; (3) reducing the light measurements using a neural network; (4) creating a generated image of test data by plotting reduced light measurements; (5) expressing a generated image as a polynomial mathematical function; (6) using a curve-fitting algorithm to generate parameters to define a generated image; (7) optimizing a reconstruction of a generated image and producing a fitted image; (8) comparing light measurements and fitted image by solving the linear regression; (9) validating one or more parameters obtained from linear regression and one or more peak heights obtained; (10) classifying a validated result as positive or negative by comparing peak heights of a clinical sample to reference samples; (11) classifying a result using a neural network; and (12) using a test result with other patient information in a decision-support system to generate a medical diagnosis or risk assessment.

29. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and



**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

emitting the light of the first wavelength from a light emitting diode;

transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip; and

transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector.

30. (Previously Presented) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

emitting the light of the first wavelength from a first light emitting diode;

transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip;

transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector;

emitting the light of the second wavelength from a second light emitting diode;

transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip; and

transmitting the third amount of light reflected from the surface of the test strip through the second fiberoptic bundle to the photodetector.

**USSN 09/717,478**  
**ANDERSON *et al.***  
**AMENDMENT AND RESPONSE**

31. (Previously Presented) The method of claim 1, wherein the reader head further comprises a second light emitting diode and a third fiberoptic bundle optically coupled to the second light emitting diode;

wherein the plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture further comprises a third portion of fiberoptic conductor ends comprising fiberoptic conductors of the third fiberoptic bundle.

32. (Previously Presented) The method of claim 5, wherein the reader head further comprises a second light emitting diode and a third fiberoptic bundle optically coupled to the second light emitting diode;

wherein the plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture further comprises a third portion of fiberoptic conductor ends comprising fiberoptic conductors of the third fiberoptic bundle.